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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,991

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Sean M. Kerwin

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MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
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EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/720,991

Applicant(s)

KERWIN, SEAN M.

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33,35 and 37 is/are rejected.
- 7) ☒ Claim(s) 34,36 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 and 32-38 are pending in the instant application.

Information Disclosure Statement

1. Applicant's Information Disclosure Statement (IDS), submitted February 3, 2005, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, attached to the instant Office Action.

Election/Restrictions

2. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to compounds of formula (I), classified in various subclasses of classes 544, 546, and 548. A further election of a single disclosed species will be required if this Group is elected.
- II. Claims 32-38, drawn to methods of preparing compounds of formula (II), classified in various subclasses of classes 544, 546, 548, and 549. A further election of a single disclosed species will be required if this Group is elected.

In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. 121 as follows:

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3. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103.

4. Where an election of Groups I or II is made, an election of a single disclosed compound (in the specification) is further required, including an exact definition of each substituent on the base molecule (Formulae I or II), wherein a **single member** at each substituent group or moiety is selected. For example, the base compound has the substituent group R^2 , wherein R^2 is recited to be any one of -H, halogen, alkyl, cyano, alkoxy, carboalkoxy, haloalkyl, etc., such that Applicant must select a single substituent for R^2 , and each subsequent variable position. In the instant case, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim that fall into the same class and subclass as the elected compound (or set of compounds). Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected species, as defined by the above Groups and common classification. Should applicant traverse on the ground that the compounds are not patentable distinct, applicant should submit

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evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and other compounds encompassed by the elected Group above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R.

1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications).

5. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37 CFR 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claims remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 DFR 1.48(b) and by the fee required under 37 DFR 1.17(I).

6. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

7. Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical

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structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions (Groups), i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Applications of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir, 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

8. Invention I is related to Invention II as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process as demonstrated in the claims, since Applicants recite three different processes of preparation in claims 40-42.

9. The Inventions of Group I are related as mutually exclusive species in the Markush group of Formula I. The species are distinct and independent from each other because the compounds

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differ structurally, one from the other as defined by the different variables recited in the claims. For example, within claim 1, the variable R^2 alone has many separate, generic possibilities, including, for example, Hydrogen, halogen, alkyl, alkoxy, etc, which cannot be said to belong to the same class and subclass of chemical classification. Absent factual evidence to the contrary, each is a different chemical compound.

10. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

11. During a telephone conversation with Mr. Mark R. DeLuca, Reg. No. 44,649, on December 27, 2006, a provisional election was made with traverse to prosecute the invention of Group II, claims 32-38, and the specific compound of example 6. Affirmation of this election must be made by applicant in replying to this Office action. Accordingly, claims 1-11 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Status of the Claims

12. Claims 1-11 and 32-28 are pending in the instant application. Claims 1-11, as previously stated, are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:

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Compounds of Formula (II), depicted in claim 32, wherein: X is N; Y is O; R¹ is phenyl, and the remaining variables are as defined.

As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 32-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), i.e. those compounds wherein both X and Y are N, and wherein R¹ is other than phenyl. The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. and international classification systems. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly and a reference that anticipates the elected compound(s) would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 32, 33, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunwell et al, J. Med. Chem. The Dunwell et al journal article teaches the synthesis of 2-aryl – substituted benzoxazole derivatives, including several schemes that read directly on the process of claim 32. Dunwell et al specifically teach the synthesis of a 2-phenyl-benzoxazole compound

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in a solvent, with the addition of an acid (i.e. polyphosphoric acid) at elevated temperatures (200 °C), please see the reaction on page 797 and description on page 799.

Claim Objections

15. Claims 32-38 are objected to for containing non-elected subject matter, and claims 34, 36, and 38 are also objected to as being dependent on a rejected base claim.

Conclusion

16. In conclusion, claims 32, 33, 35, and 37 are rejected, and claims 34, 36, and 38 are objected to.

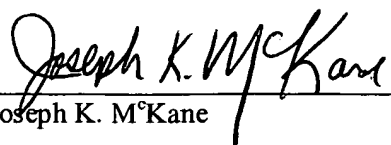
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.272.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
January 5, 2007


Joseph K. McKane

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